Section 5.0 510(k) Summary

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Date:	April 25, 2012
Trade Name:	Evolution® Colonic Stent System
Common Name:	Stent, colonic, metallic, expandable
Classification Name:	Stent, colonic, metallic, expandable (21 CFR 878.3610, Product Code: MQR)
Predicate Devices:	Boston Scientific Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery System (K000281) Boston Scientific WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System (K061877) Cook Evolution® Duodenal Stent System (K101530)

Description of the Device:	Stent Description: This flexible, self-expanding stent is constructed of nitinol wire. The total length of the stent is indicated by radiopaque markers on the inner catheter, indicating the actual length of the stent at nominal stent diameter. The stent has flanges at both stent ends. The stent is provided with a body diameter of 25mm and flange diameters of 30mm and is provided in three lengths 6cm, 8cm and 10cm. Introducer System Description: The stent is mounted on an inner catheter, which accepts a 0.035 inch wire guide and is constrained by an outer catheter. A pistol-grip delivery handle allows stent deployment or recapture. The introducer system diameter is 10 Fr and working length is 230cm.
Indications for use:	This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.
Comparison of Characteristics:	The Evolution® Colonic Stent System is substantially equivalent to the currently marketed predicate devices, the Boston Scientific Wallstent® Enteral Endoprosthesis with Unistep™ Plus Delivery System (K000281), the Boston Scientific WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System (K061877) and the Cook Evolution® Duodenal Stent System (K101530). The proposed device shares many technological characteristics with at least one of the predicate devices (or fall within the range of the predicates) in terms of the following: • Stents: o Dimensions (Diameter & Length), o Materials (i.e. nitinol), o Self Expanding Stent,

- Braided Stent Construction,
- Number of Expanded Ends.

- Introduction System:
  - Materials of construction,
  - Working length dimensions,
  - Allows stent deployment and recapture,
  - Supplied with a preloaded stent,
  - Allows placement using fluoroscopic techniques,
  - Compatibility with an endoscope
- Intended use
- All are intended for single use, are supplied sterile and are not intended to be removed.

Performance Data:

Performance (bench and clinical) testing was carried out to determine the equivalence of the Evolution® Colonic Stent System to predicate devices and to verify the safety and effectiveness of the device.

Performance Testing-Bench:

The bench testing was conducted in accordance with various applicable ASTM standards and in accordance with FDA's *Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses.* In the absence of specific colonic stent guidance this guidance was considered relevant to colonic stents.The following bench tests were carried out: deployment testing, expansion force testing, compression force testing, dimensional testing, corrosion testing, tensile strength testing and MRI testing. The bench testing was successfully completed. Results of the testing provide reasonable assurance that the Evolution® Colonic Stent System will function as intended.

Biocompatibility:

Biocompatibility testing in compliance with ISO 10993-1 and FDA's *Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses* supports the safety of the Evolution® Colonic Stent

System.

Performance Testing-Clinical:

A 80 patient registry study was conducted to compile clinical data on use of the Evolution® Colonic Stent System for palliation of symptoms due to colonic obstruction or stricture caused by malignant neoplasms, and as a "bridge to surgery" to relieve large bowel obstruction prior to potential colectomy in patients with malignant strictures. Data on clinical success, technical success, acute procedural success, implant duration, symptoms at follow-up, and adverse events were collected. Follow-up occurred to 6 months or death. The data demonstrate acceptable technical success, clinical success, acute procedural success were achieved, and symptom relief. Adverse events included perforation, migration, and obstruction. Importantly, no adverse events were associated with device malfunction and no deaths were considered to be caused by a device complication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Jacinta Kilmartin
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MAY 17 2012

Re: K113510
Trade/Device Name: Evolution® Colonic Stent System
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MQR
Dated: April 25, 2012
Received: April 30, 2012

Dear Ms. Kilmartin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4.0 Indications for Use

510(k) Number (if known): K113510

Device Name: Evolution® Colonic Stent System

Indications for Use:

This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113510